



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/944,389

09/04/2001

Paul James Davis

ISA-048.06

9864

25181

7590

05/30/2006

FOLEY HOAG, LLP

PATENT GROUP, WORLD TRADE CENTER WEST

155 SEAPORT BLVD

BOSTON, MA 02110

EXAMINER

NGUYEN, BAO THUY L

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/944,389

Applicant(s)

DAVIS ET AL.

Examiner

Bao-Thuy L. Nguyen

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 103-161 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 103-161 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. The amendment submitted on 16 March 2006 has been received. Claims 1-102 have been canceled. Claims 103-161 have been added and are pending.

#### *Priority*

2. It is agreed that the pending claims are fully supported by the foreign priority document and are entitled to a priority date of 17 February 1989.

#### *Claim Rejections - 35 USC § 112*

3. Claims 103-161 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 103, 145 and 151 are indefinite because it is unclear if the features recited in the wherein clause are positive limitations of the claimed device. Because these features are vague, it is unclear where the first binding agent is located on the test strip.

Claims 113, 142, 157 and 161 are vague because it appears that these are method steps and not positive limitations of the device.

During a conversation with Dr. Zarutskie on May 25, 2006, it was recommended that the following changes be made to clarify the claims:

103. An immunoassay test device, comprising:  
a test strip comprising:

a porous sample receiving member, configured to receive a liquid sample,

a macroporous body,

a porous carrier comprising a detection zone,

a first binding reagent for binding an analyte, the first binding reagent is immobilized in the detection zone, [and]

a labeled binding reagent comprising a particulate label portion and a binding portion for binding the analyte[;], the labeled binding reagent is disposed in the macroporous body in a dry state and is mobilizable by liquid that passes along a flow path, and

the labeled binding reagent and the first binding reagent are configured to bind the analyte and to form an immobilized and directly-detectable product in the detection zone, if the analyte is present in liquid received by the sample receiving member;

wherein,

~~[the sample receiving member is configured to received a liquid,]~~

the test strip defines a flow path along which liquid received by the sample receiving member can pass to the macroporous body and thereafter to the porous carrier,

~~[prior to use, the labeled binding reagent is disposed in a dry state in the macroporous body and is mobilizable by liquid that passes along the flow path, and~~

~~—— the labeled binding reagent and the first binding reagent are configured to bind the analyte and to form an immobilized and directly-detectable product in the detection zone, if the analyte is present in liquid received by the sample receiving member].~~

113. Cancelled.

142. Cancelled.

145. An immunoassay test device, comprising:

a test strip comprising:

a porous sample receiving member, configured to receive a liquid sample,

a macroporous body,

a porous nitrocellulose carrier comprising a detection zone,

a first binding reagent capable of specifically binding a gonadotropin compound, the first binding agent is immobilized in the detection zone, [and]

a labeled binding reagent comprising a colored particulate label portion and a binding portion for the gonadotropin compound[;], disposed in the macroporous body in a dry state and is mobilizable by liquid that passes along a flow path, and

the labeled binding reagent and the first binding reagent are configured to bind the gonadotropin compound and to form an immobilized and directly-detectable product in the detection zone, if the gonadotropin compound is present in liquid received by the sample receiving member;

wherein,

[the sample receiving member is configured to received a liquid,]

the test strip defines a flow path along which liquid received by the sample receiving member can pass to the macroporous body and thereafter to the porous nitrocellulose carrier at a location separated from the detection zone, and

[prior to use, the labeled binding reagent is disposed in a dry state in the macroporous body and is mobilizable by liquid that passes along the flow path, and

the labeled binding reagent and the first binding reagent are configured to bind the gonadotropin compound and to form an immobilized and directly-detectable product in the detection zone, if the gonadotropin compound is present in liquid received by the sample receiving member].

151. An immunoassay test device, comprising:

a test strip comprising:

a porous sample receiving member, configured to receive a liquid sample,

a macroporous body,

a porous carrier comprising a detection zone, and

a first binding reagent for binding an analyte or an analogue thereof, the first binding reagent is immobilized in the detection zone,

a labeled reagent comprising a particulate label portion and the analyte or the analogue thereof, the labeled reagent is disposed in the macroporous body in a dry state and is mobilizable by liquid that passes along a flow path, and

the labeled binding reagent and the first binding reagent are configured to form an immobilized and directly-detectable product in the detection zone,

wherein,

~~[the sample receiving member is configured to receive a liquid,]~~

the test strip defines a flow path along which liquid received by the sample receiving member can pass to the macroporous body and thereafter to the porous carrier[7]

~~[prior to use, the labeled binding reagent is disposed in a dry state in the macroporous body and is mobilizable by liquid that passes along the flow path, and~~

~~the labeled binding reagent and the first binding reagent are configured to form an immobilized and directly detectable product in the detection zone].~~

156. Cancelled.

161. Cancelled.

#### *Allowable Subject Matter*

4. Claims 103-161 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Claims 103, 145 and 151 define over the prior art of record, specifically, Eisinger et al, because Eisinger does not disclose or make obvious a device comprising in a liquid flow path, a sample receiving member, a macroporous member having labeled reagent, and a porous carrier comprising a detection zone.

#### *Conclusion*

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

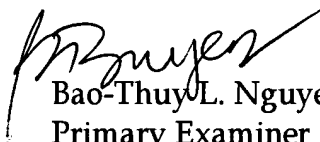
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Wednesday from 8:00 a.m. -4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Bao-Thuy L. Nguyen  
Primary Examiner  
Art Unit 1641 5/25/06